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(Not for submission under 37 CFR 1.99)

Application Number	10524963
Filing Date	2005-02-18
First Named Inventor	David William Tonge
Art Unit	1614
Examiner Name	Leslie A. Royds
Attorney Docket Number	100815-1P US

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	1	BRADBURY, Robert, H et al, "New Non-peptide Endothelin-A Receptor Antagonists: Synthesis, Biological Properties, and Structure-Activity Relationships of 5-(Dimethylamino)-N-pyridyl-, -N-pyrimidinyl, -N-pyridazinyl-, and -N-pyrazinyl-1-naphthalenesulfonamides", J Med Chem, 14 May 1997, 996-1004, 40.	☐
	2	BROOKS N. et al, "ZD4054 – a specific endothelin-A receptor antagonist providing hope for treatment of HRPC", 4th PacRim Breast and Prostate Cancer Meeting. British Columbia, Canada, 12–16 August 2008. abstract	☐
	3	CARDUCCI M.A. et al, "Targeting bone metastasis in prostate cancer with endothelin receptor antagonists", Clin Cancer Res, 2006, 6296s–6300s, 12.	☐
	4	CARDUCCI, M.A. et al, "The Endothelin-A Receptor Antagonist Atrasentan (ABT-627) Delays Clinical Progression in Hormone Refractory Prostate Cancer: a Multinational, Randomized, Double-Blind, Placebo-Controlled Trial", Asco Abstracts 2001.	☐
	5	CARRAGHER N. et al "Application of 3-dimensional (3D) in vitro invasion assays demonstrate anti-invasive activity of the specific endothelin-A (ETA) receptor-antagonist ZD4054 when combined with the novel Src/Abl inhibitor AZD0530"NCRI. Birmingham, UK, 5–8 October 2008; abst B77.	☐
	6	CHIAO, J.W. et al, "Endothelin-1 from Prostate Cancer Cells is enhanced by bone contact which blocks osteoclastic bone resorption", British Journal of Cancer, 2000, 360-365, 83(3).	☐
	7	CHIRGWIN, J.M. et al, "Tumor-bone cellular interactions in skeletal metastases", J Musculoskel Neuron Interact, 2004, 308-318, 4(3).	☐
	8	CLARKSON-JONES J. et al, "Metabolism of [14C]-ZD4054 in healthy volunteers", Drug Metab Rev, 2008, 206, 40 (Suppl 3) (Abstract 283).	☐
	9	CLARKSON-JONES J. et al, "Metabolism of [14C]-ZD4054 in healthy volunteers", poster, ISSX – 15th North American Regional Meeting, San Diego, USA, 12–16 October 2008	☐
	10	CURWEN J et al, "The impact of ZD4054, a specific endothelin-A receptor antagonist, on tumor blood supply, invasion and the bone microenvironment" Mol Cancer Ther, 2007;6(12) Suppl II:abst A272.	☐
	11	CURWEN J et al, "The impact of ZD4054, a specific endothelin-A receptor antagonist, on tumor blood supply, invasion and the bone microenvironment", AACR-NCI-EORTC, San Francisco, USA, 22–26 October 2007. Poster.	☐

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	12	CURWEN, J. et al, "The specific endothelin A receptor antagonist ZD4054 reduces tumour-induced angiogenesis in a preclinical model", 10th International Conference on Endothelin (ET-10). Bergamo, Italy, 16–19 September 2007; oral presentation	☐
	13	CURWEN, J. et al, "The specific endothelin A receptor antagonist ZD4054 reduces tumour-induced angiogenesis in a preclinical model", 10th International Conference on Endothelin (ET-10). Bergamo, Italy, 16–19 September 2007; poster	☐
	14	DAWSON N. et al, "Impact of the specific endothelin-A (ETA) receptor antagonist ZD4054 on overall survival and bone metastasis in patients with hormone-resistant prostate cancer: results of a Phase II trial", Current Treat Options Oncol 2008; 105–107, 9(Suppl 1).	☐
	15	DAWSON N. et al, "Impact of the specific endothelin-A (ETA) receptor antagonist ZD4054 on overall survival and bone metastasis in patients with hormone-resistant prostate cancer: results of a Phase II trial", oral presentation, Chemotherapy Foundation Symposium, New York, USA, 4–7 November 2008	☐
	16	DAWSON N. et al,"Impact of the specific endothelin A receptor antagonist ZD4054 on overall survival and bone metastasis in patients with hormone-resistant prostate cancer: results of a Phase II trial", ASCO GU Congress, San Francisco, USA 14–16 February 2008, Genitourinary Cancers Symposium Proceedings 2008;abst 7.	☐
	17	DAWSON N. et al,"Impact of the specific endothelin A receptor antagonist ZD4054 on overall survival and bone metastasis in patients with hormone-resistant prostate cancer: results of a Phase II trial", ASCO GU Congress, San Francisco, USA 14–16 February 2008, poster.	☐
	18	DINGEMANSE, J. et al, "Pharmacokinetics and pharmacodynamics of tezosentan, an intravenous dual endothelin receptor antagonist, following chronic infusion in healthy subjects", Br J Clin Pharmacol, 28 Apr 2002, 355-362, 53.	☐
	19	FIZAZI K.et al, "The Effects of Endothelin-1 and Abt-627, and Endothelin-1 Antagonist, in an in Vitro Model of Bone Metastases from Prostate Cancer", Asco Abstracts 2001.	☐
	20	GODARA G. et al, "Distinct Patterns of Endothelin Axis Expression in Primary Prostate Cancer", UROLOGY, 2007, 209-215, Vol 70(1).	☐
	21	GODARA G. et al, "Role of Endothelin Axis in progression to Aggressive Phenotype of Prostate Adenocarcinoma", The Prostate, 2005, 27-34, 65.	☐
	22	GROSS-GOUPIL M. et al, "Integrating Molecular Oncology into Therapeutic Strategies for Prostate Cancer", European Urology Supplements, 2009, 114–119, 8.	☐

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	23	GROWCOTT J. et al "ZD4054 – A small-molecule, specific endothelin-A receptor antagonist: providing hope for patients with hormone-resistant prostate cancer", AZ-Manchester Cancer Research Centre Showcase. Manchester, UK, 22 September 2008.	☐
	24	GROWCOTT J. et al, "Anti-invasive activity of the specific endothelin-A receptor (ETAR) antagonist, ZD4054, in A673 rhabdomyosarcoma cells", 10th International Conference on Endothelin (ET-10). Bergamo, Italy, 16–19 September 2007. Poster.	☐
	25	GROWCOTT J. et al, "Anti-invasive activity of the specific endothelin-A receptor (ETAR) antagonist, ZD4054, in A673 rhabdomyosarcoma cells", 10th International Conference on Endothelin (ET-10). Bergamo, Italy, 16–19 September 2007. Oral Presentation.	☐
	26	GROWCOTT J.W. et al, "Phenotypic in vitro differentiation of the specific endothelin A receptor antagonist, ZD4054, from the selective endothelin antagonist, atrasentan", Mol Cancer Ther, 2007; 6(12) Suppl II:abst B269.	☐
	27	GROWCOTT J.W. et al, "Phenotypic in vitro differentiation of the specific endothelin A receptor antagonist, ZD4054, from the selective endothelin antagonist, atrasentan", AACR-NCI-EORTC, San Francisco, USA, 22–26 October 2007. Poster.	☐
	28	GROWCOTT, J.W., "Preclinical anticancer activity of the specific endothelin A receptor antagonist ZD4054", Anti-Cancer Drugs 2009, 00:000–000.	☐
	29	GUISE T. et al, "Endothelin A Receptor Blackade Inhibits Osteoblastic Metastases", Asco Abstracts 2001.	☐
	30	HICKINSON D.M. et al, "Enhanced in vitro anti-invasive activity in A673 rhabdomyosarcoma cells of the specific endothelin-A receptor (ETA) antagonist ZD4054 when combined with the novel Src inhibitor AZD0530", Proc Am Assoc Cancer Res, 2008, 49 :abst 1487.	☐
	31	HICKINSON D.M. et al, "Enhanced in vitro anti-invasive activity in A673 rhabdomyosarcoma cells of the specific endothelin-A receptor (ETA) antagonist ZD4054 when combined with the novel Src inhibitor AZD0530", AACR Annual Meeting, San Diego, CA, USA, 12–16 April 2008. Poster	☐
	32	ISHERWOOD B. et al "Enhanced in vitro anti-invasive activity in A673 rhabdomyosarcoma cells of the specific endothelin-A (ETA) antagonist ZD4054 when combined with the novel Src/Abl inhibitor AZD0530" NCRI. Birmingham, UK, 5–8 October 2008; poster.	☐
	33	JAMES N, et al, "The potent, specific endothelin A receptor antagonist ZD4054 improves overall survival in patients with pain-free or mildly symptomatic M1 hormone-resistant prostate cancer" 1st European Multidisciplinary Meeting on Urological Cancers. Barcelona, Spain, 2–4 November 2007;abst O2.	☐

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	34	JAMES N. "New clinical data for the specific ETA receptor antagonist ZD4054", EAU 2008 Milan Italy, 26–29 March 2008. Oral presentation.	☐
	35	JAMES N. et al, "The effect of ZD4054 on bone metastases in patients with M1 hormone-resistant prostate cancer as assessed by radionuclide bone scans", 1st European Multidisciplinary Meeting on Urological Cancers. Barcelona, Spain, 2–4 November 2007;abst P10.	☐
	36	JAMES N. et al, "The effect of ZD4054 on bone metastases in patients with M1 hormone-resistant prostate cancer as assessed by radionuclide bone scans", 1st European Multidisciplinary Meeting on Urological Cancers. Barcelona, Spain, 2–4 November 2007. Poster.	☐
	37	James N.D. et al, "ZD4054, a potent, specific endothelin A receptor antagonist, improves overall survival in pain-free or mildly symptomatic patients with hormone-resistant prostate cancer (HRPC) and bone metastases" ECCO 14, Barcelona, Spain, 23–27 September 2007. Oral Presentation.	☐
	38	JAMES, N.D. et al, "Safety and Efficacy of the Specific Endothelin-A Receptor Antagonist ZD4054 in Patients with Hormone-Resistant Prostate Cancer and Bone Metastases Who Were Pain Free or Mildly Symptomatic: A Double-Blind, Placebo-Controlled, Randomised, Phase 2 Trial" Eur Urol (2008), doi:10.1016/j.eururo.2008.11.002.	☐
	39	JAMES, N.D. et al, "ZD4054, a potent, specific endothelin A receptor antagonist, improves overall survival in pain-free or mildly symptomatic patients with hormone-resistant prostate cancer (HRPC) and bone metastases", European Journal of Cancer Supplements, 2007, abstract 3LB, Vol. 5, No. 6.	☐
	40	KENYON A. et al, "The mystery of the co-eluting peak"; DMDG meeting. Cambridge, UK, 17–19 September 2007. Poster.	☐
	41	KNIGHT L.J. et al, "Hypermethylation of endothelin receptor type B (EDNRB) is a frequent event in non-small cell lung cancer", Proc Am Assoc Cancer Res, 2007, 48:abst 1135.	☐
	42	KNIGHT L.J. et al, "Hypermethylation of endothelin receptor type B (EDNRB) is a frequent event in non-small cell lung cancer", AACR, Los Angeles, CA, USA, 14–18 April 2007. Poster	☐
	43	KNIGHT, L.J., "Epigenetic silencing of the endothelin-B receptor gene in non-small cell lung cancer", International Journal Of Oncology, 2009, 465-471, 34.	☐
	44	KOPETZ, Scott E et al, "Endothelin-1 as a target for therapeutic intervention in prostate cancer", Investigational New Drugs, May 2002, 173-182, 20.	☐

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	45	MOHAMMAD K., et al, "Combined endothelin A receptor antagonist and bisphosphonate treatment more effectively reduces prostate cancer growth in bone than either alone", American Society for Bone and Mineral Research, 27th Annual Meeting. 2005; 1213a.	☐
	46	NELSON J.B.et al, "Endothelin-1 inhibits apoptosis in prostate cancer", Neoplasia 2005, 631-7, 7(7) (abstract).	☐
	47	NELSON J.B.et al, "The Endothelin Axis: Emerging Role In Cancer", Nature Reviews Cancer, 2003, 110-116, 3.	☐
	48	NELSON J.B.et al, "The Endothelin-A Receptor Antagonist Atrasentan (ABT-627) Reduces Skeletal Remodeling Activity in Men with Advance Refractory Prostate Cancer", Asco Abstracts 2001.	☐
	49	PAYNE H. et al, "Progression-free survival, overall survival and bone metastasis in a phase II trial of the specific endothelin a receptor antagonist ZD4054 in patients with hormone-resistant prostate cancer", CURy congress. Barcelona, Spain, 31 January – 3 February 2008. oral presentation	☐
	50	PFLUG BR et al, "Defining the basis of an operational model for enhanced efficacy of combination therapy using an endothelin receptor antagonist and chemotherapeutic agents", Mol Cancer Ther, 2007;6(12) Suppl II:abst A287.	☐

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